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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/373,585	08/13/1999	NOBUHIKO OGURA	Q55432	2737

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EXAMINER
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LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 09/373,585	<b>Applicant(s)</b> OGURA, NOBUHIKO	
	<b>Examiner</b> Frank W Lu	<b>Art Unit</b> 1634	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 1/25/2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 25 January 2006. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 6,7 and 21-33.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Advisory Action***

1. Applicant's response to the office action filed on January 25, 2006 has been entered. The claims pending in this application are claims 6, 7, and 21-33.

### ***Response to Arguments***

I. In page 6, last paragraph of applicant's remarks, applicant argues that "[T]he Examiner asserts that Stimpson teaches the aspects of claims 6 and 26. However, as previously indicated, Stimpson teaches away from the present invention. For example, in col. 2, lines 49-51, Stimpson discloses that 'since elements of the array are formed by the application of a DNA solution to the surface of the array the process is relatively slow.' This is contrary to the present invention in which binding agents are applied to the surface of a substrate. Consequently, it is unlikely that one of skill in the art would apply the teachings of the Stimpson reference in order to teach the claimed recitations".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. Since the phrase "for manufacturing a test piece for use in biological analysis of a sample organism" is an intended use of the apparatus recited in claims 6 and 26 (a functional limitation) and is not a structural limitation of claims 6 and 26, a test piece recited in claims 6 and 26 is not a part of the apparatus. Furthermore, since the phrase "test piece for use in biological analysis of a sample organism comprising a strip-like substrate bearing thereon numbers of known specific binding agents which are different from each other and are arranged in a line at predetermined intervals in the longitudinal direction of the strip-like substrate" is used to limit the test piece, the strip-like substrate and the binding agents recited in claims 6 and 26

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are not a part of the apparatus and is not a structural limitation of the apparatus recited in claims 6 and 26. Therefore, the sheet-like substrate and the binding agents recited in claims 6 and 26 are not structural elements of the apparatus and the apparatus recited in claims 6 and 26 only requires a plurality of applicators or applying means, a conveyor or conveying means and a cutting means. Note that applicant's arguments are related to sheet-like substrate and the binding agents which are not a structural element of the apparatus recited in claims 6 and 26.

II In page 7, second paragraph bridging to page 8, last paragraph of applicant's remarks, applicant argues that "the claimed **applicators** apply a reagent in lines in the longitudinal direction of the strip-like substrate. The Examiner cites Hayes for teaching the claimed applicators, however, Hayes merely indicates the use of, for example, reagent jetting heads. There is no indication that the reagent jetting heads of Hayes or that the liquid application of Stimpson, are arranged and conveyed, as recited in claim. Furthermore, in Stimpson, the reagent is applied in a direction perpendicular to a longitudinal direction of the 21.5 foot sheet (See Fig. 2C). Assuming *arguendo*, applicators are disclosed in Stimpson, there is no indication that such applicators would apply a reagent in the longitudinal direction of the strip-like substrate. The claims further recite 'cutting means which cuts the sheet-like substrate bearing thereon the plurality of specific binding agents **in the first direction** into a plurality of strips.' There is no indication that the razor of Stimpson cuts a sheet-like substrate in a first direction into a plurality of strips. In response to Applicant's argument that the functional language must be given due consideration, the Examiner now appears to be asserting that it is inherent that the applicators as taught in Hayes and Stimpson function like the claimed applicator. However, as indicated above, in Stimpson, the reagent is applied in a direction perpendicular to a longitudinal direction

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of the 21.5 foot sheet (See Fig. 2C). Assuming *arguendo*, applicators are disclosed in Stimpson, there is no indication that such applicators would apply a reagent in the longitudinal direction of the strip-like substrate. See also Applicant's claim 33. Therefore, contrary to the Examiner's assertions, it is not inherent that the applicators of Hayes and Stimpson, function as claimed. Moreover, the burden is upon the Examiner, not the Applicant, to establish that the cited references teach the claimed limitations. The Examiner further asserts that '[if] the specification defines what is meant by the limitation for the purposes of the claimed invention, the examiner should interpret the limitation as having that meaning. If no definition is provided, some judgment must be exercised in determining the scope of the limitation,' citing MPEP 2182 in support. The Examiner also states that 'since the specification does not define 'applicator means' and claim 26 only required that a plurality of applicator means are arranged at predetermined interval[s] in a first direction' that the combination of Stimpson and Hayes therefore teaches the claimed applicator means and conveyor means. Applicant directs the Examiner's attention to, for example, page 16, line 26 to page 18, line 4 of Applicant's specification, which describes the claimed applicator means and conveyor means. Consequently, upon viewing specification and its corresponding description in the drawings, it is apparent that the combination of Stimpson and Hayes does not teach the claimed applicator means and conveyor means".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, the claims do not require that "**applicators** apply a reagent in lines in the longitudinal direction of the strip-like substrate" as argued by applicant. Second, since Stimpson teach that the sheet with different DNA sample is cut with a razor blade (for example, see column 14, last paragraph), Stimpson discloses a cutting means as recited in claim

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6. Furthermore, applicant has no evidence to show that the razor of Stimpson cannot cut a sheet-like substrate in a first direction into a plurality of strips. Note that a sheet-like substrate is not a structural element of the claimed apparatus. Third, MPEP 2114 (R-1) clearly states that “[W]hile features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board’s finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). ‘[A]pparatus claims cover what a device is, not what a device does.’ *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original)” and “[A] claim containing a ‘recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus’ if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Since Stimpson as evidence by US Patent No. 4,877,745 teaches all structural limitations of claims 6 and 26 and applicant has no evidence to show that the apparatus taught by Stimpson as evidence by US Patent No. 4,877,745 cannot perform functions recited in claims 6 and 26, the examiner considers that Stimpson as evidence by US Patent No. 4,877,745 teaches all limitations recited in claims 6 and 26. Fourth, according to MPEP 2182, “[T]he ‘means or step plus function’ limitation should be interpreted in a manner consistent with the specification disclosure. If the

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specification defines what is meant by the limitation for the purposes of the claimed invention, the examiner should interpret the limitation as having that meaning. If no definition is provided, some judgment must be exercised in determining the scope of the limitation". Although page 16, line 26 to page 18, line 4 of the specification describes applicator ports and conveyor belt, the specification does not define applicator ports as applicator means and define conveyor belt as conveyor means. Thus the specification has no definition for applicator means and conveyor means. Since the specification does not define "applicator means" and claim 26 only requires that a plurality of applicator means are arranged at predetermined interval in a first direction, Stimpson as evidence by US Patent No. 4,877,745 teaches a plurality of jetting heads in the reagent jet printing is arranged at predetermined or fixed interval in an anti-clockwise direction or a clockwise direction (see US Patent No. 4,877,745, Figure 1), the plurality of jetting heads in the reagent jet printing taught by Stimpson as evidence by US Patent No. 4,877,745 is a plurality of applicator means recited in claim 26. Since the specification does not define "conveying means" and claim 26 only requires that a conveyer means conveys the plurality of applicators or a sheet-like substrate, and Stimpson teaches that an automated device to apply the multitude of reagents to a 21.5 foot sheet is assembled from an X-Y-Z table (e.g. Asymtek) fitted with a reagent dispenser and a step motor controlled take up spool and an adjustable drag pay-out spool (see column 8, third paragraph and Figure 2C ), Stimpson discloses a conveyor mean which conveys the plurality of applicators (ie., the plurality of jetting heads in the reagent jet printing) or a sheet-like substrate as recited in claim 26.

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III. In page 9, second paragraph of applicant's remarks, applicant argues that "[C]laims 23 and 24 should be deemed allowable by virtue of their dependency to claim 6 for the reasons set forth above. Moreover, Shuminov does not cure the deficiencies of Stimpson and Hayes".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. Since Stimpson as evidence by US Patent No. 4,877,745 teaches all limitations recited in claims 6, 7, 21, 22, 25-29, and 31-33 (see above arguments), Shuminov is not used to cure the deficiencies of Stimpson and Hayes.

IV. In page 9, third paragraph bridging to page 10, second paragraph of applicant's remarks, applicant argues that "[T]he Examiner cited Shuminov guide rail 50 for teaching the claimed guard rail and cited the razor of Stimpson for teaching the claimed cutting means. See Office Action at page 7. However, Stimpson col. 14, lines 51-60, describes that the spiral bundle is placed inside a metal tube whose inner diameter is slightly larger than the outer diameter of the bundle. The bundle is allowed to extend from the end of the metal tube and an array slab was cut with a razor blade using the metal tube as a guide to obtain a uniform straight cut. Therefore, it is unlikely that one of skill in the art would modify the cutting guide of Stimpson to include the guide rail 50 of Shuminov or the guide rail of Biedermann. Moreover, upon viewing the illustration of guide rail 50 of Shuminov (see Fig. 4a) it is unlikely that one of skill in the art would modify the guide rail 50 of Shuminov to form an upper body portion of the cutter 51 of Shuminov or that the guide rail 50 of Shuminov would be modified to include the guide rail 15 of Biedermann. In particular, such a modification would result in a substantial modification of the principle of operation of Shuminov".

These arguments have been fully considered but they are not persuasive toward the



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withdrawal of the rejection. First, although Stimpson uses metal tube as a guide to obtain a uniform straight cut, applicant does not indicate why one having ordinary skill in the art at the time the invention was made cannot add another guide rail into the apparatus recited in claim 6 wherein the another guide rail locates on an upper body portion of said cutting means. Second, the rejection does not indicate to modify the guide rail 50 of Shuminov to form an upper body portion of the cutter 51 of Shuminov or that the guide rail 50 of Shuminov would be modified to include the guide rail 15 of Biedermann as suggested by applicant.

2. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Frank Lu  
Primary Examiner  
February 15, 2006



**FRANK LU**  
*Primary* **PATENT EXAMINER**